

Appl. No. : **10/727,155**
Filed : **December 2, 2003**

REMARKS

Paragraphs [0003], [0064], [0221] and the table headings of Tables 31 and 32 have been amended to correct spelling or other errors. Paragraphs [0009] – [0012] and [0015] – [0017] have been amended to include sequence identifiers for the CDR sequences previously disclosed therein. Thus, no new matter has been added by way of this amendment.

Claims 44, 45, 47- 49, 50, 51, 57, 59, 60, 62, 67, 68, 70- 72, 74, 75, 77, 81, 82, 84, 85, 87 and 91-106 have been canceled by way of this amendment. Applicants maintain that the cancellation of a claim makes no admission as to its patentability. Applicants reserve the right to pursue the subject matter of the canceled claims in this or any other patent application. Claims 44, 45, and 47-51 remain withdrawn. Claims 58, 61, 63-66, 69, 73, 76, 78-80, 83, and 86, 88-90 have been amended by way of this amendment. New Claims 107-127 have been added. Support for the amended and new claims can be found throughout the specification and claims as originally filed, for example, at paragraphs, [0009], [0010], [0021], [0031]-[0034], [0036], [0039], [0043], [0050], [0063], and [0095], [0126], [0135], and Tables 1, 31 and 32. Thus, no new matter has been added by way of this amendment. Claims 44, 45, 47-51, and 58, 61, 62-66, 69, 73, 76, 78-80, 83, and 86, 88-90, and 107-127 are pending.

Applicants thank the Examiner for indicating that Claims 58, 66, 73, and 83 would be allowable if rewritten in independent form including all of the claim limitations of the base claim and any intervening claims. Applicants have amended these claims as indicated by the Examiner by way of this amendment.

Applicants respectfully submit that the above amendments along with the remarks below place the pending product claims in condition for allowance. Applicants note that the Examiner previously required restriction between product and process claims. Because amended Claims 58, 66, 73, 83 and new Claim 122, drawn to novel antibodies, are believed to be in condition for allowance, Applicants have canceled the withdrawn method claims. The canceled method claims will be pursued in a divisional application. Applicants maintain that the cancellation of a claim makes no admission as to its patentability. Applicants reserve the right to pursue the subject matter of the canceled claims in this or any other patent application.

In response to the Office Action mailed on May 30, 2006, Applicants submit the following remarks.

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Discussion of Amendments to the Specification

The Examiner objected to the specification, requiring that all spelling, TRADEMARK, and like errors be corrected. As suggested by the Examiner, Applicants have amended paragraphs [0003] and [0064] to correct a spelling error. Likewise, Applicants have amended trademarks designated in paragraph [0221] and the table headings of Tables 31 and 32 to include the ® symbol. Applicants respectfully submit that these amendments place the specification in condition for allowance, and request withdrawal of the objection to the specification.

Rejections under 35 U.S.C. § 112, second paragraph

Claims 59, 60, 62, 63, 67, 68, 75, 77, 78, 84, 85, 87, 88, 93, 95, 96, 99 and 103 were rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicants regard as the invention.

A. Claims 60, 68, 75, 85, 99, and 103, and dependent claims thereof, are allegedly indefinite in the recitation of “299v2,” “299v1,” “263,” and “269” because their characteristics are allegedly not known. The Office asserts that these terms are laboratory designations which do not clearly define the claimed products because laboratories may use the same designations to define completely distinct materials.

Applicants respectfully disagree, and submit that those of ordinary skill in the art would recognize these designations to refer to specific antibodies described in the instant application. Applicants have taught how to make and use each of these antibodies. Nevertheless, in the interest of advancing the instant application to allowance, Applicants have canceled the rejected claims rendering the rejection moot.

B. Claims 59, 67, 74, 84, and 93, and dependent claims thereof, are allegedly indefinite in the recitation of “wherein said antibody, or binding fragment thereof, is a complete antibody,” because a binding fragment of an antibody is not a complete antibody.

In the interest of advancing the instant application to allowance, Applicants have canceled the rejected claims thus rendering the rejection under this section moot.

New claims 111, 114, 117, 120, and 126 recite, in relevant part, “wherein said antibody is an IgG2 antibody.” Support for this amendment can be found throughout the application as

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originally, filed, for example at paragraph [0126] and [0135]. Accordingly, no new matter has been added by way of this amendment.

C. Claims 62, 77, 87, and 95 are allegedly indefinite in the recitation of “wherein the antibody, or binding fragment thereof, is a binding fragment of an antibody,” because a binding fragment of an antibody is not a complete antibody.

In the interest of advancing the instant application to allowance, Applicants have canceled the rejected claims thus rendering this rejection moot.

New Claims 110, 113, 116, 119, and 125 recite, in relevant part, “wherein said binding fragment comprises a Fab, Fab’, F(ab’)₂, or Fv fragment.” Support for this amendment can be found throughout the specification as originally filed, for example, at paragraphs [0036] and [0095]. Thus, no new matter has been added by way of this amendment.

D. Claims 63, 78, 88, and 96, and dependent claims thereof, are allegedly indefinite in the recitation of “wherein said antibody is conjugated to a therapeutic agent” because there is insufficient antecedent basis for this limitation.

As suggested by the Examiner, Applicants have amended Claims 63, 78, and 88 to be in independent form, and recite, “A conjugate” in the preamble. Claim 96 has been canceled by way of this amendment for reasons unrelated to the patentability of the subject matter of this claim. New Claim 107 similarly recites “A conjugate” in the preamble. Accordingly, Applicants believe this rejection has been overcome. Withdrawal of the rejection and allowance of the pending claims is respectfully requested.

E. Claims 61, 69, 76, 86, 94, 102, and 106 are allegedly indefinite in the recitation of “wherein the antibody is in association with a pharmaceutical carrier.” The Examiner contends that the base claims from which the rejected claims depend recite “a fully human monoclonal antibody,” which is a compound, not a composition of an antibody and a pharmaceutically acceptable carrier.

As suggested by the Examiner, Applicants have amended Claims 61, 69, 76, and 86 to be independent claims, which recite “a composition” in the preamble. Claims 94, 102, and 106 have been canceled by way of this amendment for reasons unrelated to the patentability of the subject matter of these claims. Thus, Applicants believe this rejection has been overcome. Withdrawal of the rejection and allowance of the pending claims is respectfully requested.

Rejections under 35 U.S.C. § 112, first paragraph, Enablement

Claims 57, 60-65, 68, 70-72, 75-82, 85-98, and 99-106 were rejected under 35 U.S.C. § 112, first paragraph, as allegedly failing to comply with the enablement requirement.

A. Claims 60, 68, 75, 85, and 99-106 are rejected because it is alleged that to practice the claimed invention, anti-TNF α antibodies 299v2, 299v1, 263 and 269 are required and therefore must be known and readily available to the public or obtainable by a repeatable method set forth in the specification.

Applicants strongly disagree with the rejections of these claims and submit that Claims 60, 68, 75, 85, and 99-106 are fully enabled by the instant specification because the specification provides more than sufficient information required to obtain anti-TNF α antibodies 299v2, 299v1, 263 and 269, including, but not limited to, the variable region sequences for these antibodies. Accordingly, deposit of these antibodies is not necessary. Nevertheless, in the interest of advancing the instant application to allowance, Applicants have canceled these claims. Rendering the rejection under this section moot.

B. Claims 57, 61-65, 70-72, 76-82, and 86-98 are rejected because it is alleged that one of skill in the art would not know how to make a “fully human monoclonal antibody, or binding fragment thereof, that binds Tumor Necrosis Factor- α , wherein the antibody or binding fragment thereof, comprises” a particular light chain or heavy chain without further specifying a complementary light chain or heavy chain. Specifically, it is alleged that one of skill in the art would need to know the sequences of both the heavy and light polypeptide chains because formation of an intact antigen-binding site generally requires the association of the complete heavy and light chain variable regions of a given antibody.

Applicants respectfully disagree with the rejection of these claims. Nevertheless, in the interest of advancing the instant application to allowance, Applicants have canceled independent Claims 57, 72 and 82 and rewritten dependent Claims 58, 66, 73 and 83 in independent form including all of the limitations of canceled Claims 57, 72, and 82. The Examiner has indicated that such an amendment would place these claims in condition for allowance. In addition, Applicants have amended Claims 61-65, 76-80, and 86-90 to correct the dependencies therein. Claims 70, 71, 81, and 91-98 have been canceled by way of this amendment for reasons unrelated

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to the patentability of the subject matter of these claims. Thus, the amended claims recite both a heavy and light chain polypeptide. In addition, new Claim 122 recites each of the heavy and light chain complementarity determining regions (CDRs), which the Office indicates are critical in maintaining the antigen binding specificity and affinity which is characteristic of the parent immunoglobulin. Finally, new Claims 108 and 109 recite both a heavy and light chain polypeptide. Accordingly, Applicants respectfully submit that this rejection has been overcome. Applicants respectfully request allowance of the pending claims.

Rejections under 35 U.S.C. § 112, first paragraph, New Matter

Claims 59, 60, 67, 68, 74, 75, 84, 85, and 93 were rejected under 35 U.S.C. § 112, first paragraph, as allegedly failing to comply with the written description requirement. Specifically, the Examiner asserts that the specification as originally filed does not provide support for "complete antibody."

Applicants respectfully disagree with this rejection and submit that the specification provides ample support for both full-length, intact antibodies and binding fragments thereof. Nevertheless, in the interest of advancing the instant application to allowance, Applicants have canceled the rejected claims. Accordingly, the rejection under this section is moot.

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CONCLUSION

For the foregoing reasons, it is respectfully submitted that the rejections set forth in the outstanding Office Action have been addressed and that the pending claims are in condition for allowance. Accordingly, Applicants request the expeditious allowance of the pending claims.

The undersigned has made a good faith effort to respond to all of the rejections in the case and to place the new claims in condition for immediate allowance. Nevertheless, if any undeveloped issues remain or if any issues require clarification, the Examiner is respectfully requested to call the undersigned to discuss such issues.

Please charge any additional fees, including any fees for additional extension of time, or credit overpayment to Deposit Account No. 11-1410.

Respectfully submitted,

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